

535,009

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



Rec'd PCT/PTO

13 MAY 2005



(43) International Publication Date
3 June 2004 (03.06.2004)

PCT

(10) International Publication Number
WO 2004/045587 A1

(51) International Patent Classification⁷:
31/569

A61K 9/36,

(74) Agent: VAN DEN BROEK, Ludovicus A.G.M.; P.O.
BOX 20, NL-5340 BH OSS (NL).

(21) International Application Number:
PCT/EP2003/050829

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR,
CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD,
GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR,
KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN,
MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU,
SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(22) International Filing Date:
13 November 2003 (13.11.2003)

(25) Filing Language:
English

(26) Publication Language:
English

(30) Priority Data:
60/427,740 20 November 2002 (20.11.2002) US
02079920.1 20 November 2002 (20.11.2002) EP

(84) Designated States (regional): ARIPO patent (BW, GH,
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE,
SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (for all designated States except US): AKZO
NOBEL N.V. [NL/NL]; Velperweg 76, NL-6824 BM Arnhem (NL).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2004/045587 A1

(54) Title: PHARMACEUTICAL TABLETS CONTAINING TIBOLONE AND A COATING

(57) Abstract: The present invention relates to a stabilized pharmaceutical tablet comprising an amount of from 0.1 to 10% by weight of fbolone provided with a coating, such as a film coating, a sugar coating, a sugar film coating or a "wrap" coating. The invention further relates to the use of a coating for stabilizing a pharmaceutical tablet comprising tibolone. Preferably, the coating is a sugar coating or a sugar film coating. Preferably, the sugar comprises sucrose. These tablets were shown to have a lower amount of OM38, i.e. an isomerization degradation product of fbolone, after storage as compared to uncoated fbolone tablets.